

WE CLAIM:

1. A method comprising:
- 5 a) adding one or more reagents to a test sample from a patient comprising at least part of a blood sample from the patient in order to cause formation of a complex comprising at least one acute phase protein and at least one human lipoprotein, while causing substantially no fibrin polymerization;
- 10 b) measuring the formation of said complex over time so as to derive a time-dependent measurement profile; and
- 15 c) determining a slope and/or total change in the time-dependent measurement profile so as to diagnose a condition of the patient.
2. The method according to claim 1, wherein said reagent comprises a metal ion.
- 20 3. The method according to claim 2, wherein said metal ion is a divalent metal ion.
- 25 4. The method according to claim 3, wherein said divalent metal ion is a metal ion from the transition elements.
- 30 5. The method according to claim 2, wherein said metal ion comprises one or more of calcium, magnesium, manganese, iron or barium.
- 35 6. The method according to claim 1, wherein a clot inhibitor is provided as part of said reagent or as part of an additional reagent added to said test sample.

7. The method according to claim 6, wherein said clot inhibitor comprises one or more of hirudin, heparin, PPACK, I2581, and antithrombin.

5 8. The method according to claim 1, wherein the formation of said complex is correlated to the increase probability of death of the patient.

10 9. The method according to claim 8, wherein the greater the formation of said complex, the greater the likelihood of death of the patient.

15 10. The method according to claim 1, wherein the time dependent measurement profile is an optical transmission profile, and wherein the greater the decrease of optical transmittance through the test sample, the greater the formation of said complex, and the greater the likelihood of mortality of the patient.

20 11. The method according to claim 1, wherein said at least one human lipoprotein comprises one or more of chylomicrons or remnants thereof, VLDL, IDL, LDL or HDL, and wherein said at least one acute phase protein comprises CRP and/or SAA.

25 12. The method according to claim 11, wherein the diagnosing of the condition of the patient comprises a prediction of the likelihood of mortality of the patient.

30 13. The method according to claim 1, wherein said reagent is added to said test sample in the absence of clot inducing reagents.

35 14. The method according to claim 1, wherein the formation of the precipitate is measured at

least once after time\_0.

15. The method according to claim 14, wherein a  
single endpoint measurement is made of  
precipitate formation after time\_0.

16. The method according to claim 1, wherein said  
reagent is capable of causing precipitate  
formation completely in the absence of fibrin  
polymerization.

17. The method according to claim 10, wherein the  
amount of fibrin polymerization in the method,  
if any, causes no change in optical  
transmittance.

18. A method for predicting an increased likelihood  
of system failure or mortality of a patient,  
comprising:

- a) obtaining a blood sample from a  
patient;
- b) obtaining plasma or serum from said  
blood sample;
- c) adding a reagent capable of inducing  
the formation of a protein complex  
comprising at least one lipoprotein and  
at least one acute phase protein;
- d) taking one or more measurements of a  
parameter of the plasma or serum and  
correlating the measured parameter to  
complex formation if present;
- e) correlating the formation of the  
complex to an increased likelihood of  
system failure or mortality of the  
patient.

19. The method according to claim 18, wherein a

plurality of measurements are made after addition of said one or more reagents in order to derive a time-dependent measurement profile.

5 20. The method according to claim 18, wherein a single reagent is used prior to taking said measurements.

10 21. The method according to claim 18, wherein said measurements are measurements of optical transmission or absorbance through said sample.

15 22. The method according to claim 21, wherein said reagent comprises a metal ion.

23. The method according to claim 22, wherein said metal ion comprises one or more of calcium, magnesium, manganese, iron or barium.

20 24. The method according to claim 18, wherein a clot inhibitor is provided as part of said one or more reagents.

25 25. The method according to claim 24, wherein said clot inhibitor comprises one or more of hirudin, heparin, PPACK, I2581 or antithrombin.

30 26. The method according to claim 18, wherein said one or more measurements are unaffected by clot formation due to lack of fibrin polymerization.

35 27. The method according to claim 18, wherein the one or more measurements are a plurality of measurements, and wherein a rate of change of said plurality of measurements or a total change is determined, and wherein haemostatic dysfunction is determined based on the

determined total and/or rate of change.

5 28. The method according to claim 18, wherein said at least one lipoprotein comprises VLDL, IDL and/or LDL, and said at least one acute phase protein comprises SAA and/or CRP.

10 29. The method according to claim 28, wherein a majority of said complex comprises CRP bound to VLDL.

15 30. The method according to claim 18, wherein the prediction of the increased likelihood of system failure or mortality is more accurate than in the absence of steps a) to e).

20 31. The method according to claim 18, wherein steps a) to e) are performed at least once more at a later time in order to determine patient condition regression or progression.

25 32. A method comprising:  
a) adding one or more reagents to a test sample comprising at least a component of a blood sample from a patient in order to cause formation of a precipitate comprising an acute phase protein and a lipoprotein;  
30 b) measuring the precipitate comprising the acute phase protein and the lipoprotein;  
c) adding an inhibiting reagent, before or after adding said one or more precipitate causing reagents, which inhibits at least in part the  
35 formation of the precipitate; and  
d) determining the extent of inhibition

of said inhibiting reagent.

5 33. The method of claim 32, wherein said precipitate inhibiting reagent is added after all or substantially all of the lipoprotein has become associated with acute phase protein so as to form said precipitate.

10 34. The method of claim 32, wherein said precipitate inhibiting reagent is added prior to adding the precipitate causing reagent.

15 35. The method of claim 32, wherein said precipitate inducing reagent is a divalent metal cation.

20 36. The method of claim 35, wherein said precipitate inhibiting reagent comprises one or more of an apolipoprotein capable of binding to CRP, a phosphorylcholine, , EDTA, sodium citrate, or an antibody capable of binding to a lipoprotein-acute phase protein binding site.

25 37. The method of claim 36, wherein said precipitate inhibiting reagent is capable of inhibiting the association of CRP with chylomicrons or remnants thereof, LDL, VLDL and/or IDL.

30 38. The method of claim 37, wherein the determining of the extent of inhibition is performed over time so as to derive a time-dependent measurement profile.

35 39. The method of claim 38, wherein the measurement over time is a measurement of optical

transmittance or absorbance over time.

40. A method comprising:

- a) providing a test sample from a test subject;
- b) adding a reagent to said test sample in order to cause formation of a complex of one or more lipoproteins and one or more acute phase proteins;
- c) measuring the formation of the complex;
- d) correlating the formation of the complex to a concentration of said one or lipoproteins.

41. The method of claim 40, wherein said reagent comprises a divalent metal cation and an acute phase protein.

42. The method of claim 41, wherein said acute phase protein is CRP.

43. The method of claim 41, wherein said one or more lipoproteins is chylomicrons, VLDL and/or IDL.

44. The method of claim 41, wherein the formation of the complex and the formation of the additional complex are measured over time so as to provide respective first and second time-dependent measurement profiles.

45. The method of claim 40, wherein the measured additional complex and the measured initial complex together are correlated to a total amount of acute phase protein in the test sample.

46. The method of claim 44, wherein the acute phase protein is C-reactive protein.

5 47. The method of claim 40, wherein the measured initial complex is correlated to a likelihood of system failure and/or mortality.

10 48. The method of claim 46, wherein the greater the initial complex measured, the greater the likelihood of system failure and/or mortality.

49. A method for testing the effectiveness of a therapeutic, comprising:

- 15 a) providing from a test subject a test sample to be tested for complex formation;
- b) adding a reagent which causes formation of a complex of acute phase protein and lipoprotein present in said test sample;
- 20 c) administering to said test subject a therapeutic;
- d) repeating steps a) and b); and
- e) determining if the amount of complex formed has changed.